REMARKS

In the Office Action dated September 19, 2006, the Examiner states that this application contains claims directed to more than one species of the generic invention. The Examiner alleges that these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The Examiner alleges that the present application contains claims directed to the following patentably distinct species:

1. Gastrointestinal and urogenital flora.

The Examiner requires that Applicants choose one specifically named bacterial flora as recited in claim 2. The Examiner states that at least claims 1 and 9 are generic.

2. *L. rhamnosus, L. acidophilus, L. fermentum, L. casei, L. reuteri, L. crispatus, L. plantarum, L. paracasei, L. jensenii, L. gasseri, L. cellobiosis, L. brevis, L. delbrueckii, L. helveticus, L. salivarius, L. collinoides, L. buchneri, L. rogosae, or L. bifidum.*

The Examiner requires that Applicants choose one specifically named second probiotic organism as recited in claims 5 and 11. The Examiner states that at least claims 1 and 9 are generic.

3. Orally or vaginally.

The Examiner requires that Applicants choose one specifically named method of administration as recited in claim 8.

In order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect, with traverse, to urogenital flora as specifically named bacterial flora, *L. rhamnosus* as specifically named second probiotic organism, and oral administration as

specifically named method of administration, for further prosecution. However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

A requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." Emphasis added. PCT Rule 13.2 states: "The expression "technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." Emphasis added.

The Examiner alleges that the species of bacterial flora are independent or distinct because there are methods comprising establishing a healthy flora in gastrointestinal and urogenital mucosa wherein different strain of microbiota dominate.

The Examiner alleges that the species of second probiotic organism are independent or distinct because there are methods comprising establishing species of *Lactobacillus* drawn to different effects as a result of comprising different genes.

The Examiner alleges that the species of administration routes are independent or distinct because there are methods comprising different modes of operation, each being used indifferent capacities, have different functions and produce different effects as a result of the route of administration. The Examiner contends that oral administration is a type of systemic administration reaching most body organs and a mucosal administration is localized to a specific tissue in the body.

Applicants respectfully submit that the present invention recognizes methods and compositions for the establishment and maintenance of a healthy urogenital flora. Specifically, the invention provides at least one *Lactobacillus iners*, which enhances the flora's ability to out-compete urogenital pathogens. One aspect of the present invention is directed to a method for establishing a healthy urogenital flora in females throughout life by administering a therapeutically effective amount of at least one *Lactobacillus iners* and a pharmaceutically acceptable carrier. In another aspect of the present invention, the method further includes administering a therapeutically effective amount of a second probiotic organism.

Applicants respectfully submit that unique recognition of the present invention provides the basis for developing therapeutic products and protocols for the establishment and maintenance of a healthy urogenital flora. The species required for restriction are merely different aspects of one single inventive concept. For example, establishing gastrointestinal or urogenital flora in females throughout life by administering a therapeutically effective amount of at least one *Lactobacillus iners* are two different ways to the establishment and maintenance of a healthy urogenital flora. The administration of species of different second probiotic organisms employs the same inventive concept and technical feature of the present invention. Moreover, Applicants respectfully submit that oral and vaginal administration routes are merely two different aspects in employing the same single concept of the present invention. Oral administration is a natural means of how probiotic organisms get to the vagina (via natural passage along the rectal skin which is a mere 4cm from the vaginal perineal skin), while vaginal administration can deliver a higher dose of probiotic organisms directly onto vagina or urogenital tract. At most, oral and vaginal administrations employ the same technical feature with different doses.

Accordingly, it is respectfully submitted that all claims presented in the present application share the technical feature of the establishment and maintenance of a healthy urogenital flora. It is submitted that the present claims, when considered as a whole, defines a contribution over the prior art, and should be examined in the same application.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness among the species defined in the three groups, one from the other, as presented by the Examiner.

Accordingly, it is respectfully submitted that claims 1-19 satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

Peter I. Bernstein
Registration No. 43,497

SCULLY, SCOTT, MURPHY & PRESSER, P.C.
400 Garden City Plaza-STE 300
Garden City, New York 11530
(516) 742-4343
PIB/ZY:ab